

What we claim is:

1) A lateral flow immunoassay device for detecting immunoreactions, said device comprising:

a test strip, said test strip comprising:

a sample site for applying a sample comprising biologically active materials, said  
5 biologically active materials selected from the group consisting of antigens and antibodies;

a colorimetric labeling site for labeling the sample, forming a colorimetric immuno complex,  
said colorimetric labeling site comprising a colorimetric label positioned downstream from said  
sample site ; and

at least one reaction site positioned downstream from said colorimetric labeling site, said at  
10 least one reaction site comprising reactive biological substances which binds said colorimetric  
immuno-complexes when said biologically active materials of said sample react positively with the  
biological substances.

2) The lateral flow immunoassay device of claim 1, wherein said test strip further comprises a  
15 membrane support having a testing layer on the surface thereof, wherein said membrane support is  
comprised of a material selected from the group consisting of plastic, cardboard, nitrocellulose and  
combinations thereof.

3) The lateral flow immunoassay device of claim 2, wherein said testing layer further comprises a  
20 sample site to which the sample is applied.

4) The lateral flow immunoassay device of claim 3, further comprising a sample pad residing on

top of the testing layer, to which the sample is transferred.

5) The lateral flow immunoassay device of claim 1, wherein said colorimetric labeling site is a colorimetric labeled analyte to which the sample is being tested.

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6) The lateral flow immunoassay device of claim 5, wherein said colorimetric label is selected from the group consisting of a metal sol particle, a dyed labeled microparticle, a fluorescent labeled microparticle, and combinations thereof.

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7) The lateral flow immunoassay device of claim 6, wherein said metal sol particle may be selected from the group consisting of platinum, gold, silver, selenium, and copper.

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8) The lateral flow immunoassay device of claim 5, wherein said analyte is selected from the group consisting of antigens, antibodies, bacteria, viruses, protozoa, parasites, autoimmune antigens, heat shock proteins, transplantation antigens, histocompatibility antigens, and combinations thereof.

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9) The lateral flow immunoassay device of claim 8, wherein said analyte is selected from the group consisting of H. pylori, Streptococcus Group A, Streptococcus Group B, Mycobacterium tuberculosis, Mycoplasma, Chlamydiae, Rickettsiae, Herpes virus, CMV, Hepatitis A, Hepatitis C, Hepatitis B, Influenza, HIV I, HIV II, HTLV I & II, Chagas, Toxoplasma, Helminh, Nematodes, autoimmune antigens, heat shock proteins, transplantation antigens, histocompatibility antigens, and combinations thereof.

10) The lateral flow immunoassay device of claim 1, further comprising at least one binding site downstream from said colorimetric or fluorometric labeling site.

11) The lateral flow immunoassay device of claim 10, wherein said at least one reaction site comprises at least three reaction sites, said reaction sites comprising:

an anti-IgA binding site;

an anti-IgM binding site; and

an anti-IgG binding site.

12) The lateral flow immunoassay device of claim 11, further comprising a control site, said control site containing substances that readily react with any colorimetric or fluorometric compound.

13) The lateral flow immunoassay device of claim 11, wherein anti-Ig immunoglobulin antibodies specific for specific antibodies are positioned at said anti-Ig binding sites.

14) The lateral flow immunoassay device of claim 13, wherein said anti-Ig immunoglobulin antibodies are from affinity purification of immune sera selected from the group consisting of goats, rabbits, donkeys, sheep, chickens, and other animals.

15) The lateral flow immunoassay device of claim 13, wherein said anti-Ig immunoglobulin antibodies are monoclonal antibodies specific for IgM, IgA, IgE, and IgG antibodies.

16) The lateral flow immunoassay device of claim 11, further comprising substances reactive with IgG.

5 17) The lateral flow immunoassay device of claim 13, further comprising substances reactive with IgG, combined with said antibody.

18) The lateral flow immunoassay device of claim 16, wherein said substances are selected from the group consisting of protein A, protein G, lentil lectin, jacalin, concanavilin A, anti-IgG, mannan binding protein, wheat germ lectin, peanut lectin, avidchrom, and combinations thereof.

10 19) The lateral flow immunoassay device of claim 4, further comprising an IgG reacting substance.

15 20) The lateral flow immunoassay device of claim 19, wherein said IgG reacting substance is selected from the group consisting of protein A, protein G, an antibody to IgG, lentil lectin, jacalin, concanavilin A, mannan binding protein, wheat germ lectin, peanut lectin, avidchrom, and combinations thereof.

21) The lateral flow immunoassay device of claim 1, when said colorimetric labeling site comprises labeled anti-IgE antibodies.

20 22) The lateral flow immunoassay device of claim 21, further comprising a plurality of said reaction sites, each said reaction site being an allergen site, wherein each allergen site has a different

immobilized allergen.

23) The lateral flow immunoassay device of claim 22, wherein said immunoassay comprises at least one test strip.

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24) The lateral flow immunoassay device of claim 22, wherein said allergens are selected from the group consisting of pollens, dust mite allergens, molds, animal epithelium, foods, allergen mixes, and combinations thereof.

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25) The lateral flow immunoassay device of claim 22, wherein said allergens are immobilized on the test strip by the use of solubilizing agents.

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26) The lateral flow immunoassay device of claim 25, wherein said solubilizing agents are selected from the group consisting of sugars and alcohols, which allow for the unfolding of the allergen protein tertiary structure such that more hydrophobic domains are exposed allowing increased binding to the membrane, and increased reactivity to the IgE antibody.

27) A lateral flow immunoassay device for detecting immune reactants, said device comprising:

a test strip, said test strip comprising:

a sample site for applying a sample comprising antibodies;

a colorimetric labeling site for labeling the sample, forming a colorimetric antibody complex,

said colorimetric labeling site comprising a colorimetric labeled analyte positioned downstream from

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said sample site ; and

at least four reaction sites positioned downstream from said colorimetric labeling site, wherein said there is a reaction site for detecting IgG antibodies, a reaction site for detecting IgA antibodies, a reaction site for detecting IgM antibodies, and a control reaction site, wherein each said reaction site binds said colorimetric immune-antibody complexes when said antibodies of said sample specific for each said reaction site are present in said sample, whereupon a colored line will appear at each reaction site where said antibodies of said sample have been bound to said colorimetric labeled analyte.

28) The lateral flow immunoassay device of claim 27, wherein said colorimetric label is selected from the group consisting of a metal sol particle, a dyed labeled microparticle, a fluorescent labeled microparticle, and combinations thereof.

29) The lateral flow immunoassay device of claim 28, wherein said metal sol particle may be selected from the group consisting of platinum, gold, silver, selenium, and copper.

30) The lateral flow immunoassay device of claim 27, wherein said analyte is selected from the group consisting of antigens, antibodies, bacteria, viruses, protozoa, parasites, autoimmune antigens, heat shock proteins, transplantation antigens, histocompatibility antigens, and combinations thereof.

31) The lateral flow immunoassay device of claim 30, wherein said analyte is selected from the group consisting of H. pylori, Streptococcus Group A, Streptococcus Group B, Mycobacterium,

Tubercle bacillus, Mycoplasma, Chlamydiae, Rickettsiae, Herpes virus, CMV, Hepatitis A, Hepatitis C, Hepatitis B, Influenza, HIV I, HIV II, HTLV I & II, Chagas, Toxoplasma, Helminths, Nematodes, autoimmune antigens, heat shock proteins, transplantation analytes, histocompatibility antigens, and combinations thereof.

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32) The lateral flow immunoassay device of claim 27, further comprising a control site, said control site containing substances that readily react with the colored solid phase.

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33) The lateral flow immunoassay device of claim 27, wherein anti-Ig immunoglobulin antibodies specific for specific antibodies are positioned at said anti-Ig binding sites.

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34) The lateral flow immunoassay device of claim 33, wherein said anti-Ig immunoglobulin antibodies are from affinity purification of immune sera selected from the group consisting of goats, rabbits, donkeys, sheep, chickens, and other animals.

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35) The lateral flow immunoassay device of claim 33, wherein said anti-Ig immunoglobulin antibodies are monoclonal antibodies specific for IgM, IgA, IgE, and IgG antibodies.

36) The lateral flow immunoassay device of claim 33, further comprising substances reactive with IgG.

37) The lateral flow immunoassay device of claim 33, further comprising substances reactive with

IgG, combined with said antibody.

38) The lateral flow immunoassay device of claim 36, wherein said substances are selected from the group consisting of protein A, protein G, lentil lectin, jacalin, concanavilin A, anti-IgG, mannan binding protein, wheat germ lectin, peanut lectin, avidchrom, and combinations thereof.

39) The lateral flow immunoassay device of claim 27, further comprising an IgG reacting substance at said sample site..

40) The lateral flow immunoassay device of claim 39, wherein said IgG reacting substance is selected from the group consisting of protein A, protein G, an antibody to IgG, lentil lectin, jacalin, concanavilin A, mannan binding protein, wheat germ lectin, peanut lectin, avidchrom, and combinations thereof

41) A lateral flow immunoassay device for detecting immune reactants, said device comprising:  
a test strip, said test strip comprising:  
a sample site for applying a sample comprising antibodies;  
a colorimetric labeling site for labeling the sample, forming a colorimetric antibody complex, said colorimetric labeling site comprising a colorimetric labeled anti-IgE antibody, said colorimetric labeling site positioned downstream from said sample site ; and

a plurality of reaction sites downstream from said labeling site, each said reaction site containing a different allergen such that when IgE antibodies labeled with colorimetric labeled anti-



IgE antibodies come in contact with an antigen to which the IgE antibodies react, the reaction site will develop a colored line, indicating a positive response.

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42) The lateral flow immunoassay device of claim 41, when said colorimetric labeling site comprises labeled anti-IgE antibodies.

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43) The lateral flow immunoassay device of claim 41, further comprising a plurality of said reaction sites, each said reaction site being an allergen site, wherein each allergen site has a different immobilized allergen.

44) The lateral flow immunoassay device of claim 41, wherein said immunoassay comprises at least one test strip.

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45) The lateral flow immunoassay device of claim 43, wherein said allergens are selected from the groups consisting of pollens, dust mite allergens, molds, animal epithelium, foods, allergen mixes, and combinations thereof.

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46) The lateral flow immunoassay device of claim 43, wherein said allergens are immobilized on the test strip by the use of solubilizing agents.

47) The lateral flow immunoassay device of claim 46, wherein said solubilizing agents are selected from the group consisting of sugars and alcohols, which allow for the unfolding of the allergen

protein tertiary structure such that more hydrophobic domains are exposed allowing increased binding to the membrane, and increased reactivity to the IgE antibody.

48) A lateral flow immunoassay device for detecting immune reactants, said device comprising:

5 a test strip, said test strip comprising:

a sample site for applying a sample comprising antibodies;

a fluorescent labeling site for labeling the sample, forming a fluorescent antibody complexes, said fluorometric labeling site comprising a fluorescent labeled analyte positioned downstream from said sample site ; and

10 at least four reaction sites positioned downstream from said fluorescent labeling site, wherein said there is a reaction site for detecting IgG antibodies, a reaction site for detecting IgA antibodies, a reaction site for detecting IgM antibodies, and a control reaction site, wherein each said reaction site binds said fluorescent antibody complexes when said antibodies of said sample specific for each said reaction site are present in said sample, whereupon a fluorescent line appears at each  
15 reaction site where said antibodies of said sample have been bound to said fluorescent labeled analyte.

49) The lateral flow immunoassay device of claim 48, wherein said analyte is selected from the group consisting of antigens, antibodies, bacteria, viruses, protozoa, parasites, autoimmune antigens,  
20 heat shock proteins, transplantation antigens, histocompatibility antigens, and combinations thereof.

50) The lateral flow immunoassay device of claim 49, wherein said analyte is selected from the

group consisting of H. pylori, Streptococcus Group A, Streptococcus Group B, Mycobacterium ,  
Tubercle bacillus, Mycoplasma, Chlamydiae, Rickettsiae, Herpes virus, CMV, Hepatitis A, Hepatitis  
C, Hepatitis B, Influenza, HIV I, HIV II, HTLV I & II, Chagas, Toxoplasma, Helminths,  
Nematodes, autoimmune antigens, heat shock proteins, transplantation antigens, histocompatibility  
antigens, and combinations thereof.

51) The lateral flow immunoassay device of claim 48, further comprising a control site, said control  
site containing substances that readily react with any fluorescent compound.

52) The lateral flow immunoassay device of claim 48, wherein anti-Ig immunoglobulin antibodies  
specific for specific antibodies are positioned at said anti-Ig binding sites.

53) The lateral flow immunoassay device of claim 52, wherein said anti-Ig immunoglobulin  
antibodies are from affinity purification of immune sera selected from the group consisting of goats,  
rabbits, donkeys, sheep, chickens, and other animals.

54) The lateral flow immunoassay device of claim 52, wherein said anti-Ig immunoglobulin  
antibodies are monoclonal antibodies specific for IgM, IgA, IgE, and IgG antibodies.

55) The lateral flow immunoassay device of claim 54, further comprising substances reactive with  
IgG.

56) The lateral flow immunoassay device of claim 54, further comprising substances reactive with IgG, combined with said antibody.

57) The lateral flow immunoassay device of claim 56, wherein said substances are selected from the group consisting of protein A, protein G, lentil lectin, jacalin, concanavilin A, anti-IgG, mannan binding protein, wheat germ lectin, peanut lectin, avidchrom, and combinations thereof.

58) The lateral flow immunoassay device of claim 48, further comprising an IgG reacting substance at said sample site.

59) The lateral flow immunoassay device of claim 58, wherein said IgG reacting substance is selected from the group consisting of protein A, protein G, an antibody to IgG, lentil lectin, jacalin, concanavilin A, mannan binding protein, wheat germ lectin, peanut lectin, avidchrom, and combinations thereof

60) A lateral flow immunoassay device for detecting immunoreactants, said device comprising:  
a test strip, said test strip comprising:  
a sample site for applying a sample comprising antibodies;  
a fluorescent labeling site for labeling the sample, forming a fluorescent antibody complex,  
said fluorescent labeling site comprising a fluorescent labeled anti-IgE antibody, said fluorescent labeling site positioned downstream from said sample site ; and  
a plurality of reaction sites downstream from said labeling site, each said reaction site

containing a different allergen such that when IgE antibodies labeled with fluorescent labeled anti-IgE antibodies come in contact with an antigen to which the IgE antibodies react, the reaction site will develop a fluorescent line, indicating a positive response.

5 61) The lateral flow immunoassay device of claim 60, when said fluorescent labeling site comprises labeled anti-IgE antibodies.

10 62) The lateral flow immunoassay device of claim 60, further comprising a plurality of said reaction sites, each said reaction site being an allergen site, wherein each allergen site has a different immobilized allergen.

15 63) The lateral flow immunoassay device of claim 60, wherein said immunoassay comprises at least one test strip.

64) The lateral flow immunoassay device of claim 62, wherein said allergens are selected from the group consisting of pollens, dust mite allergens, molds, animal epithelium, foods, allergen mixes, and combinations thereof.

20 65) The lateral flow immunoassay device of claim 62, wherein said allergens are immobilized on the test strip by the use of solubilizing agents.

66) The lateral flow immunoassay device of claim 65, wherein said solubilizing agents are selected

from the group consisting of sugars and alcohols, which allow for the unfolding of the allergen protein tertiary structure such that more hydrophobic domains are exposed allowing increased binding to the membrane, and increased reactivity to the IgE antibody.